PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DUROBAC (TABLETS)

80 mg Trimethoprim and 400 mg Sulphamethoxazole.

DUROBAC DOUBLE STRENGTH (TABLETS)

160 mg Trimethoprim and 800 mg Sulphamethoxazole.

Sugar free

Contains preservative: Nipastat

Read all of this leaflet carefully before you start taking DUROBAC.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **DUROBAC** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. **What DUROBAC is and what is it used for:**

   DUROBAC and DUROBAC DS contains two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. As **DUROBAC** only works against some types of bacteria, it is only suitable for treating some types of infections.

   It can be used to treat:

   - Upper and lower lung infections
   - Urinary bladder or urinary tract infections
   - Gastrointestinal tract (your mouth, oesophagus (gullet), stomach and intestines) infections
   - Genital tract (reproductive track including sexually transferred diseases) infections.

- Skin infections
- Other infections caused by bacteria that **DUROBAC** works against

2. What you need to know before you take DUROBAC:

Do not take DUROBAC if :

- You are allergic (hypersensitive) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients in **DUROBAC** (listed in section 6).
- you have been told that you have porphyria.
- you have severe liver or severe kidney problems.
- you have been told that you have an anaemia due to not having enough folic acid.
- you are pregnant or breastfeeding.

Warnings and precautions

Take special care with DUROBAC if you:

- are suffering from AIDS or are having special treatment that lowers your immune system, e.g. after an organ transplant. You can experience more severe side-effects.
- have skin rashes, often accompanied by flu-like symptoms after taking **DUROBAC**. The rash may progress to widespread blistering or peeling of the

skin. This can be a serious skin reaction to **DUROBAC.** Stop taking **DUROBAC** and seek urgent advice from your doctor.

- don't have enough folic acid (a vitamin) in your body, which can make your skin pale and make you feel tired, weak and breathless. Your doctor might prescribe additional folic acid with your **DUROBAC** treatment.
- are elderly you may have more severe side effects, e.g. problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g. thiazides.
- have kidney problems, your doctor might reduce the **DUROBAC** dosage (see section 3). You should take enough fluids , especially if you are on high dosages of **DUROBAC**.
- are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to **DUROBAC** as well.

Other medicines and DUROBAC:

Always tell your healthcare professional if you or your child are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines medicine (this includes complementary or traditional medicines.):

- are taking any of the following, as the effect of these medicines can become stronger and your doctor might monitor you more closely or need to change your treatment:
    - Warfarin or other medicines to thin your blood.
    - Methotrexate, used to treat certain cancers or certain diseases affecting your immune system.
    - Phenytoin, used to treat epilepsy.
    - Sulfonylurea compounds, used to treat diabetes.
    - Digoxin or procainamide to treat problems with the way your heart beats.
    - Tolbutamide and repaglinide used to treat diabetes.
- Para-aminobenzoic acid (PABA) is a supplement and can increase your risk of side effects, e.g. crystals forming in your urine.
- Cyclosporin, used in e.g. kidney transplant, as it can cause your kidneys to work less effective.
- Pyrimethamine used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g. anaemia.
- Zidovudine used in the treatment of HIV, as it can increase your risk of develop less blood cells.
- Lamivudine used in the treatment of HIV, as **DUROBAC** at high dosages can increase the effect of lamivudine.

- Medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets, which help increase the amount of urine you produce, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems). These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folinic acid, a supplement can lower the effect of **DUROBAC.**
- Contraceptives can become less effective when taking with **DUROBAC**. You should use additional protection while on **DUROBAC** treatment.
- Azathioprine used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease. Your doctor might monitor your blood cells more closely.

DUROBAC with food, drink, and alcohol:

The tablets should be swallowed with a glass of water and food.
Drink plenty of fluid such as water while you are taking **DUROBAC**.

Pregnancy and breastfeeding and fertility:

The safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **DUROBAC**.

You should not take **DUROBAC** while you are pregnant or breastfeeding your baby.

Driving and using machines:

It is not always possible to predict to what extent **DUROBAC** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **DUROBAC** affects them.

DUROBAC contains Nipastat

DUROBAC contains Nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

3. How to take DUROBAC:

Do not share medicines prescribed for you with any other person.
Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.
If you have the impression that the effect of **DUROBAC** is too strong or too weak, tell your doctor or pharmacist.

The usual dose is:

DUROBAC

Adults and children over 12 years:

- Two tablets every 12 hours after meals.
- The maximum dose (for particularly severe cases) is three **DUROBAC** tablets every 12 hours.
- The minimum dosage for long term treatment is one **DUROBAC** tablet every 12 hours.

DUROBAC D/S

Adults and children over 12 years:

- One tablet every 12 hours after meals.
- The maximum dose (for particularly severe cases) is one and a half **DUROBAC D/S** tablets every 12 hours.
- The minimum dosage for long term treatment (more than 14 days) is half a **DUROBAC D/S** tablet every 12 hours.

Renal Impairment

Your doctor will do a blood test and calculate your dosage depending on the results.

No Information is available for children with renal failure.

If you take more DUROBAC than you should:

When taken more **DUROBAC** than you/they should, you may feel nausea, vomit, dizzy and confused. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of DUROBAC:

Try to take **DUROBAC** as prescribed by your healthcare professional. However, if you miss a dose, do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DUROBAC can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **DUROBAC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching)
- Severe blistering of the skin, pain and pruritus (itchy skin). These serious skin reactions includes toxic epidermal necrolysis (Lyell's syndrome), Steven-Johnson syndrome (SJS), systemic lupus erythematosus and “Fixed Drug Eruptions” to name a few (see also section 2).
- Unexpected worsening of cough and shortness of breath.
- Increase in liver enzymes (blood tests) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite,

feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

- Sudden headache or stiffness of your neck, accompanied by fever. This can be aseptic meningitis.

These are all very serious side effects. If you have them, you may have had a serious reaction to **DUROBAC**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Sulfamethoxazole

Frequent side effects:

- A fungal infection called thrush or candidiasis which can affect the mouth or vagina
- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- Headache
- Nausea
- Diarrhoea
- Rash

Less frequent side effects:

- Pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- Changes in the blood cells, resulting in feeling weak, tired or listless, pale skin, and more frequent infections
- Hypothyroidism where the thyroid doesn't create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures.
- Low blood sugar
- Low sodium concentration in your blood
- Decreased appetite
- Build-up of acid in your body (metabolic acidosis)
- Depression
- Seeing strange or unusual sights (hallucination)
- Psychotic disorder (a mental state in which you may lo Loss of balance and coordination (ataxia)
- Dizziness
- Feeling tired
- Difficulty to sleep
- Tingling or numbness in your hands and feet
- Seizures
- Vision disorders, seeing flickering or flashing lights

- Sort-sighted for a short period
- Inflammation of the eye which causes pain and redness
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- Vomiting
- Swollen and inflamed tong
- Inflamed and sore mouthse touch with reality)
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (Pancreatitis)
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Arthralgia (pains in the joints)
- Myalgia (pains in the muscles)
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual.
- Blood or cloudiness in your urine
- Kidney problems

Trimethoprim

Frequent side effects

- Headache

- Itchy skin
- Rash
- Fever,
- Nausea
- Vomiting
- Sore mouth

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse drug Reaction reporting Form", found online under SAHPRA's publications : https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **DUROBAC**.

5. How to store DUROBAC

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

- Store **DUROBAC** at or below 25 °C in original container. Protect from light and moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What DUROBAC contains:

The active substance are: trimethoprim and sulfamethoxazole

The other ingredients are: Hydrogenated vegetable oil, magnesium stearate, nipastat, pregelatinized starch maize, purified water, sodium carboxymethyl starch, starch maize.

What DUROBAC looks like and contents of the pack

DUROBAC: Flat, white bisected tablets with bevelled edges.

DUROBAC DOUBLE STRENGTH: White, oblong, biconvex, bisected tablets.

DUROBAC: 28 or 56 tablets packed in a L.D.P.E “ziploc” plastic patient ready packs and 100, 500 or 1000 tablets packed in HDPE containers.

DUROBAC D/S: 30 or 100 tablets packed in white securitainers and 1000 tablets packed in HDPE containers.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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2091

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DUROBAC DOUBLE STRENGTH: P/20.2/55

Access to the corresponding Professional information is contained in the packaging.